No. 04-623

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONERS

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QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of any state law purporting to authorize such distribution.

PARTIES TO THE PROCEEDING

Petitioners are Alberto R. Gonzales, Attorney General of the United States, Karen Tandy, Administrator of the Drug Enforcement Administration, Kenneth W. McGee, Assistant Special Agent-In-Charge of the Portland Office of the Drug Enforcement Administration, the United States of America, the United States Department of Justice, and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, David Malcolm Hochhalter, John Doe #1, and Don W. James.

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BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-63a) is reported at 368 F.3d 1118. The order of the district court granting respondents' motion for summary judgment (Pet. App. 64a-97a) is reported at 192 F. Supp. 2d 1077.

JURISDICTION

The judgment of the court of appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004 (Pet. App. 98a-99a). The petition for a writ of certiorari was filed on November 9, 2004, and was granted on February 22, 2005. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and the implementing regulation, 21 C.F.R. 1306.04, are set forth in the appendix to the petition. Pet. App. 149a-161a. Relevant provisions of the Oregon Death With Dignity Act, Or. Rev. Stat. §§ 127.800-127.995

(2003), are also set forth in the appendix to the petition. Pet. App. 162a-165a.

STATEMENT

1. a. The Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, was enacted in 1970 to provide stronger federal controls over drugs and other substances that are susceptible to abuse. Comprehensive Drug Abuse Prevention and Control (Controlled Substances) Act of 1970, preamble, 84 Stat. 1236; H.R. Rep. No. 1444, 91st Cong., 2d Sess. 1 (1970) (House Report). The CSA establishes a federal scheme that comprehensively regulates the manufacture, distribution, and possession of controlled substances. The CSA thus makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1).[1]

To dispense controlled substances lawfully, a physician or other practitioner must "obtain from the Attorney General a registration." 21 U.S.C. 822(a)(2). The CSA authorizes the Attorney General to deny or revoke the registration of a practitioner "if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f); accord 21 U.S.C. 824(a)(4). In determining the "public interest" for registration purposes, the Attorney General considers a number of factors, including the registrant's compliance with federal, state, and local laws relating to controlled substances and "such other conduct which may threaten the public health and safety." 21 U.S.C. 823(f).

Registered physicians or other practitioners may dispense controlled substances only "in the course of professional practice or research," 21 U.S.C. 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," 21 U.S.C. 822(b). A physician who dispenses controlled substances outside the "accepted limits" of medical practice is subject to prosecution under 21 U.S.C. 841(a)(1). *United States* v. *Moore*, 423 U.S. 122, 142 (1975).

[1] Under the CSA, the term "dispense" includes the issuance of a prescription by a practitioner as well as delivering a controlled substance directly to a patient. 21 U.S.C. 802(10).

Under the CSA, each controlled substance is placed on one of five schedules, depending on whether the substance has a currently accepted medical use in treatment in the United States, the relative abuse potential of the substance, and the extent to which abuse of the substance may lead to physical or psychological dependence. 21 U.S.C. 812. The Act imposes varying regulatory restrictions on controlled substances depending on the applicable schedule. Substances in schedule I—the most restricted schedule—have "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1). Human consumption of schedule I controlled substances is permissible only in a research setting where the research has been approved by the Food and Drug Administration (FDA) and the researcher has obtained from the Drug Enforcement Administration (DEA) a registration authorizing the specific research protocol. 21 U.S.C. 355(i) (2000 & Supp. II 2002), 823(f); see *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 491 (2001). By contrast, substances in schedules II through V have a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B), and therefore may be dispensed for medical use. 21 U.S.C. 829. With narrow exceptions not relevant here, substances in schedules II, III, and IV may be dispensed only pursuant to the "prescription of a practitioner." 21 U.S.C. 829(a) and (b).

When the CSA was enacted in 1970, Congress made an initial assignment of controlled substances to the schedules it

believed appropriate. 21 U.S.C. 812(c). Congress authorized the Attorney General, in consultation with the Secretary of Health and Human Services, to add or remove substances or to transfer substances from one schedule to another based upon statutory criteria that take into account changes in medical and scientific understanding and shifts in patterns of abuse. 21 U.S.C. 811, 812. In addition, Congress provided the Attorney General with broad authority to promulgate "rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. 821, and "any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the Act, 21 U.S.C. 871(b); see 21 U.S.C. 828(a) (making it "unlawful for any person to distribute" certain controlled substances except pursuant to an order form issued by the Attorney General in accordance with "regulations prescribed by him"). The Attorney General has delegated his functions under the Act to the Administrator of the DEA. 28 C.F.R. 0.100(b).

States remain free to enact their own laws relating to controlled substances, such as their own criminal penalties, but state laws are preempted to the extent of any "positive conflict" between a provision of state law and the CSA such that the two "cannot consistently stand together." 21 U.S.C. 903.

b. When the CSA became effective in 1971, DEA's predecessor (the Bureau of Narcotics and Dangerous Drugs) issued regulations to implement the Act through notice-and-comment rulemaking. One of those regulations, now found at 21 C.F.R. 1306.04(a),[2] requires that in order "to be effective," a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." A "purported prescription" that is not issued "in the usual course of professional treatment or in legitimate and authorized research" does not qualify as a "prescription within the meaning * * * of * * * 21 U.S.C. 829," and, if issued knowingly, will subject the practitioner "to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. 1306.04(a).

[2] This regulation was initially codified at 21 C.F.R. 306.04(a), see 36 Fed. Reg. 7799 (1971), and subsequently recodified at 21 C.F.R. 1306.04, see 38 Fed. Reg. 26,609 (1973).

As this Court noted in *Moore*, the requirement that a controlled substance be prescribed for a legitimate medical purpose may be implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is, in any event, made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See *Moore*, 423 U.S. at 137-139 & n.13. Essentially the same requirement flows from the fact that a physician issuing a prescription under the CSA must act "in the course of professional practice or research." 21 U.S.C. 802(21); accord 21 U.S.C. 844(a) (forbidding possession of controlled substances except "pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice"). Certain reporting requirements imposed by the CSA similarly define a "valid prescription" as one "issued for a legitimate medical purpose by an individual practitioner * * * acting in the usual course of the practitioner's professional practice." 21 U.S.C. 830(b)(3)(A)(ii). Indeed, a central condition for the lawful manufacture, distribution, or dispensing of a substance under schedules II through V is that the substance "has a currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B), and (5)(B).

2. In November 1994, Oregon voters passed a ballot initiative referred to as the Oregon Death with Dignity Act (DWDA), Or. Rev. Stat. §§ 127.800-127.995 (2003). The DWDA allows, as a matter of Oregon law, the prescribing and dispensing of "medication" for the purpose of enabling

an individual with a terminal disease to commit suicide. *Id.* §§ 127.800(11), 127.897. It requires the physician prescribing or dispensing the lethal substance to ensure that the patient is a resident of Oregon, is competent, has a terminal disease with less than six months of life-expectancy, and is making a voluntary and informed decision to obtain the substance for the purpose of ending his or her life. See *id.* §§ 127.800, 127.815. A second physician must also verify most of those facts. *Id.* §§ 127.815(d), 127.820. The DWDA provides that a physician who prescribes or dispenses a lethal amount or combination of drugs in accordance with the DWDA shall not "be subject to civil or criminal liability or professional disciplinary action" for doing so. *Id.* § 127.885(1). The DWDA thus "exempt[s] physicians who comply [with the DWDA's requirements] * * * from prosecution under [Or. Rev. Stat. § 163.125(1)(b)]," which otherwise makes it a crime under Oregon law for anyone, including a physician, to aid a suicide. *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994). Oregon is the only State in the Union that purports to authorize physician-assisted suicide.

3. In 2001, the Attorney General sought an opinion from the Office of Legal Counsel (OLC) in the Department of Justice on the question whether prescribing drugs for the purpose of assisting in a person's suicide, as contemplated in Oregon's DWDA, would constitute a valid prescription pursuant to the CSA and its implementing regulations. On June 27, 2001, OLC issued a memorandum concluding that "assisting in suicide is not a 'legitimate medical purpose' that would justify a physician's dispensing controlled substances consistent with the CSA." Pet. App. 130a; see *id.* at 106a-148a.[3]

[3] No interpretive rule had previously been issued by the Attorney General on this subject. As OLC noted in its memorandum to the Attorney General, the Administrator of the DEA had previously responded to a query from the Chairman of the House of Representatives Committee on the Judiciary by stating that assisting suicide in accordance with the DWDA would violate the CSA, see Pet. App. 108a & n.5, but then-Attorney General Janet Reno indicated a different conclusion in a subsequent letter to the Committee Chairman, see *id.* at 109a & n.7; Patients' Br. in Opp. 50a. Neither of those letters was published in the Federal Register.

The OLC memorandum explained that "[t]he CSA establishes a uniform, nation-wide statutory scheme for regulating the distribution of controlled substances," Pet. App. 130a, and noted that this Court had held, in *Oakland Cannabis*, that a California voter initiative purporting to recognize a medical use for marijuana as a matter of California law could not provide the basis for an implied "medical necessity" exception or defense in the CSA in the face of Congress's placement of marijuana in schedule I, which is for substances with "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B). Pet. App. 131a-133a. The OLC memorandum concluded that Oregon's ballot initiative likewise could not immunize a physician from federal prosecution or loss of registration under the CSA, if the Attorney General determined, pursuant to the regulatory authority granted to him in the CSA, that assisting an individual to commit suicide does not constitute a "legitimate medical purpose" for which controlled substances can be prescribed. *Id.* at 133a-134a.

The OLC memorandum also canvassed the views of medical and nursing associations, federal and state law, and judicial opinions and concluded, based on that review, that despite the Oregon voters' approval, physician-assisted suicide is not a "legitimate medical purpose." Pet. App. 114a. The memorandum explained that "state law and policy, with the sole exception of Oregon's, emphatically oppose assisted suicide," *id.* at 117a, and that federal law likewise prohibits such conduct in federal medical facilities and denies federal financial assistance in support of it, *id.* at 119a-122a. For example, the memorandum noted that the Health Care Financing

Administration in the Department of Health and Human Services had determined that physician-assisted suicide is not eligible for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." *Id.* at 121a (internal quotation marks omitted).[4] In addition, the OLC memorandum reviewed the position of leading organizations of the medical profession, including the American Medical Association, American Nurses Association, and American Psychiatric Association, all of which took the view that physician-assisted suicide was "fundamentally incompatible with the physician's role as healer." *Id.* at 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)).

On November 9, 2001, the Attorney General published an interpretive rule in the Federal Register (66 Fed. Reg. 56,607) that adopted the analysis of the OLC Memorandum. Pet. App. 100a-105a. The Attorney General determined that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR § 1306.04," and therefore that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." *Id.* at 102a. The Attorney General made clear that those conclusions "appl[y] regardless of whether state law authorizes or permits such conduct by practitioners or others." *Ibid.*[5]

4. The State of Oregon and others challenged the Attorney General's interpretive rule in the United States District

[4] The Health Care Financing Administration is now called the Centers for Medicare and Medicaid Services (CMS). CMS maintains this policy at present, and it is currently reflected in the *Medicare Benefit Policy Manual* ch. 16, § 20 (2003) <http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp>.

[5] The Attorney General distinguished assisted suicide from pain management and made clear that the latter, including "providing sufficient dosages of pain medication necessary to eliminate or alleviate pain," "has long been recognized as a legitimate medical purpose justifying physicians' dispensing of controlled substances." Pet. App. 103a.

Court for the District of Oregon. That court held the interpretive rule invalid and enjoined its application. Pet. App. 64a-97a. The federal parties appealed.

The court of appeals first held that the district court had lacked jurisdiction over respondents' suit. *Id.* at 2a-3a & n.1, 56a-61a. However, the court of appeals treated the action as a petition for review under 21 U.S.C. 877 that had been mistakenly filed in district court and transferred to the court of appeals. Pet. App. 2a-3a & n.1, 56a-61a. The court noted that there was a question whether any parties other than the health care practitioner parties had standing to challenge the Attorney General's interpretive ruling. *Id.* at 3a & n.2. In light of its determination that the practitioners could properly challenge the rule, the court of appeals declined to address whether the State of Oregon or patients also had standing. *Ibid.* On the merits, a divided panel granted the petitions for review.

a. The majority concluded that the interpretive rule was invalid absent an "unmistakably clear" indication of congressional intent to regulate physician-assisted suicide, because, in the majority's view, the rule "invokes the outer limits of Congress' power" by altering "the usual constitutional balance between the States and the Federal Government." Pet. App. 12a-13a (quoting *Solid Waste Agency* v. *United States Army Corps. of Eng'rs*, 531 U.S. 159, 172-173 (2001), and *Gregory* v. *Ashcroft*, 501 U.S. 452, 461 (1991) (citations and internal quotation marks omitted)). The court also held that the interpretive rule violates "the plain language of the CSA," *id.* at 13a, which, according to the majority, (1) only addresses "drug abuse," *id.* at 13a-14a, (2) establishes a principle of non-preemption, *id.* at 14a, (3) entrusts medical decisions to the Secretary of Health and Human Services (not the Attorney General), *id.* at 15a, and (4) requires the Attorney General to address all five statutory factors in 21 U.S.C. 823(f), including, in particular, whether the physician's con-

duct complies with state law, before adopting an interpretive rule that would affect physician registration under the CSA, Pet. App. at 16a. The court also found that the Attorney General's interpretive ruling, which it had already held to exceed the scope of his statutory authority, was not entitled to deference. *Id.* at 21a-23a. The panel therefore granted the petitions for review and "continued" the district court's injunction. *Id.* at 25a.

b. Senior Judge Wallace dissented. Pet. App. 25a-63a. He noted the presumption that Congress does not make the application of federal statutes dependent on state law, *id.* at 36a (citing *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989)), and observed that, while a physician's compliance with state law is relevant under the CSA in determining whether his or her registration would be consistent with the public interest, *id.* at 37a (citing 21 U.S.C. 823(f)(3) and (4)), other factors, including whether the physician's conduct "may threaten the public health and safety," are not dependent on state law, *ibid.* (citing 21 U.S.C. 823(f)(5)). The dissent further noted that, while the Secretary of Health and Human Services is specifically delegated certain functions under the CSA, responsibility under the Act for determining whether a physician's registration is consistent with the public interest is assigned to the Attorney General alone. *Id.* at 39a-40a.

Judge Wallace also rejected the majority's suggestion that application of the CSA to the dispensing of controlled substances to assist suicide is at the limits of Congress's power or would alter federal-state relations. Pet. App. 45a. He noted, rather, that Congress's authority under the Commerce Clause to regulate the distribution of controlled substances is well established. *Id.* at 49a-50a. Finally, the dissent observed that the Attorney General's conclusion that physician-assisted suicide is not a legitimate medical purpose

is well supported by an "overwhelming historical, legal, and medical consensus." *Id.* at 56a.

c. The court of appeals denied the government's petition for rehearing and rehearing en banc. Pet. App. 98a-99a.

SUMMARY OF ARGUMENT

The court of appeals acknowledged that the Controlled Substances Act prohibits practitioners from prescribing or dispensing controlled substances except for a "legitimate medical purpose" and "in the usual course of professional treatment." Pet. App. 5a (quoting 21 C.F.R. 1306.04). Respondents nonetheless seek to overturn the Attorney General's determination that the prescription of controlled substances, not for ordinary treatment, but for the express purpose of ending an individual's life, does not constitute a legitimate medical purpose or treatment under federal law. Respondents essentially submit that the Attorney General's interpretation of federal law would frustrate the purposes of a state-law voter initiative, and so the federal law must yield. Thus, the issue presented in this case is "who gets to decide," *id.* at 9a, whether a practitioner's conduct comports with this requirement of *federal law*—the Attorney General, pursuant to a uniform national standard, or each of the 50 States, according to 50 different views regarding the proper use of controlled substances. The text and structure of the CSA, as well as general principles of federalism, make clear that the Attorney General's interpretation of federal law need not yield to Oregon's contrary policy choices.

It is well established that the federal government, rather than the States, normally defines the terms in federal laws, giving them a single, nationwide definition. See *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30 (1989). There is no basis to depart from this general rule in interpreting the terms "legitimate medical purpose" and "treatment" in the context of the CSA. To the contrary, it is clear that Congress intended the CSA to set uniform nationwide

minimum standards for controlled substances, and, in light of the centrality of the "legitimate medical purpose" and "treatment" limitations to the entire federal scheme, those terms must also be given a uniform federal meaning.

Indeed, decisions of this Court already recognize that the CSA establishes national rules that do not yield to contrary medical policy that an individual State might seek to follow as a matter of state law. In *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), the Court made clear that the federal determination that marijuana has no "accepted medical use in treatment in the United States" foreclosed the assertion of a "medical necessity" defense to a federal prosecution under the CSA, despite a California law purporting to recognize a valid medical use of marijuana and to permit its use in certain circumstances.

There is no reason to believe that a different result is required when federal law determines that a drug has *a* legitimate medical purpose, but that not all uses of that drug are legitimate. This Court, for example, upheld a CSA conviction based on a physician's prescription of a schedule II drug—one that has a recognized and accepted medical use—for illegitimate purposes and did so on the basis of a national standard for medical practice. See *United States* v. *Moore*, 423 U.S. 122 (1975).

The conclusion that the Attorney General reached on this issue—that assisting suicide is *not* a legitimate medical purpose—finds overwhelming support in tradition, history, law, and medical expertise. The Attorney General's conclusion is consistent with the laws of 49 States, other laws and policies of the federal government, and leading associations of the medical profession. These facts alone demonstrate that the Attorney General's conclusion is reasonable and therefore must be upheld in light of the deference to which his views are entitled.

In the decision below, the court of appeals majority ignored the *Mississippi Band* line of cases, and declined to follow *Oakland Cannabis* and *Moore* in upholding the uniform national scope of the CSA. The court concluded that in order for the federal government to regulate controlled substances in a way that limits the practice of medicine in Oregon, a clear Congressional statement of its intent to do so was necessary. Pet. App. 11a. Citing *Gregory* v. *Ashcroft*, 501 U.S. 452, 460 (1991), the court of appeals held that a clear statement is necessary whenever federal law impacts upon an area within the traditional regulatory authority of the States, such as the practice of medicine. Pet. App. 11a. But *Gregory* applies only to federal laws that have an impact upon essential aspects of State sovereignty, such as the tenure of judges and location of a State's Capital. To expand *Gregory* to all areas of private conduct traditionally regulated by the States, as the court of appeals did here, would dramatically expand the clear statement requirement to encompass virtually all areas of federal regulation, in light of the breadth of the States' traditional police powers. The *Lochner*-era authority that the court of appeals cited for the proposition that certain categories of activity are presumptively beyond the authority of the federal government has long ago been rejected by this Court as both unworkable and unfounded, and there is no basis for resurrecting it now.

The court of appeals' belief that the Attorney General's ruling implicates the presumption against preemption, Pet. App. 14a-15a, was similarly misplaced. It is not "preemption" for the federal government to prohibit conduct as a matter of federal law that a particular State would deem permissible under its own laws. Oregon is free to decriminalize assisted suicide as a matter of Oregon law, as it has done. But Oregon could not displace contrary federal law by prefacing its state statutes with the phrase "notwithstanding any provision of federal law," and no presumption against

preemption allows it to exempt its physicians from compliance with federal directives sub silentio. Federal law does not yield even when it frustrates the purposes of state law.

There is no basis in the statutory language or purpose of the CSA for subordinating the Attorney General's ability to administer the Act's comprehensive national scheme for controlling dangerous substances to the views of each of the States regarding those substances' permissible uses.

ARGUMENT

I. THE CONTROLLED SUBSTANCES ACT ESTABLISHES A COMPREHENSIVE AND UNIFORM NATIONAL SYSTEM FOR REGULATING CONTROLLED SUBSTANCES, AND THE ATTORNEY GENERAL'S INTERPRETIVE RULING IMPLEMENTING THE ACT IS SUPPORTED BY THE OVERWHELMING WEIGHT OF AUTHORITY

A. The Prohibition On Dispensing Controlled Substances For Other Than A "Legitimate Medical Purpose" In The "Usual Course Of Professional Treatment" Is Central To The Regulatory Scheme Established By The Controlled Substances Act

The CSA prohibits a practitioner from prescribing controlled substances except "for a legitimate medical purpose" and "in the usual course of professional treatment." Pet. App. 5a (quoting 21 C.F.R. 1306.04). Those limitations appear throughout the CSA, reflecting their centrality to the comprehensive national scheme Congress established to regulate controlled substances. The starting point of the Act (indeed, its first provision) is the recognition that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. 801(1). And the entire federal scheme for regulating controlled substances is built upon the dual principles that the dispensing of controlled substances should be allowed for

such "legitimate medical purpose[s]," but that their distribution for illegitimate purposes should be prohibited. *Ibid.*

The Attorney General is charged under the CSA, 21 U.S.C. 811(a), with assigning controlled substances to the appropriate "schedule" according to whether they have a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b), and other factors. A substance for which the Attorney General has determined there is "no currently accepted medical use in treatment in the United States" is placed in schedule I, 21 U.S.C. 812(b)(1)(B), and may not be prescribed or dispensed except pursuant to a research protocol specifically approved by the Attorney General and the Secretary of Health and Human Services to ensure the substance will not be diverted from "legitimate medical or scientific use," 21 U.S.C. 823(f). Substances in other schedules may be dispensed by practitioners only because they have "a currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B), and (5)(B), thereby underscoring the centrality of "medical use" in "treatment" as a necessary condition for allowing a scheduled substance to be dispensed at all.

Other provisions of the Act similarly confine a practitioner's latitude in dispensing drugs in schedules II through V to legitimate medical uses in the course of treatment. The CSA makes it unlawful for "any person" to "dispense" a controlled substance "[e]xcept as authorized" by the CSA. 21 U.S.C. 841(a) and (a)(1). The Act defines "dispense" to include the "prescribing" of a controlled substance by a "practitioner," 21 U.S.C. 802(10), and defines "practitioner" to include a professionally-licensed physician dispensing controlled substances "in the course of professional practice," 21 U.S.C. 802(21). The CSA reiterates the "in the course of * * * professional practice" limitation in other provisions concerning the misuse of federal order forms, 21 U.S.C. 828(e), and unlawful possession of controlled substances, 21 U.S.C.

844(a). The "legitimate medical purpose" requirement is also reiterated in 21 U.S.C. 823(a)(1), which requires the Attorney General to ensure that there is an "adequate * * * supply" of schedule I and schedule II substances "for legitimate medical, scientific, research, and industrial purposes."

Consistent with those various provisions of the Act, the Attorney General's regulation confirms that a prescription for a controlled substance "must be issued for a legitimate medical purpose" and that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription" within the meaning of the CSA. 21 C.F.R. 1306.04(a).

This Court has similarly recognized and enforced the CSA's prohibition on the prescription of controlled substances for other than legitimate medical purposes. In *United States* v. *Moore*, 423 U.S. 122 (1975), the Court unanimously held that physicians violate the CSA "when their activities fall outside the usual course of professional practice." *Id.* at 124; see *id.* at 141-142 ("provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits"). In so holding, the Court noted that "[t]he medical purpose requirement," which is explicit in 21 U.S.C. 829(c), could be implicit in 21 U.S.C. 829(a) and (b) and is, in any event, made explicit with respect to those provision by the Attorney General's regulation, now codified at 21 C.F.R. 1306.04(a). 423 U.S. at 137 n.13. Following *Moore*, the courts of appeals have consistently applied a "legitimate medical purpose" standard in CSA prosecutions of physicians and pharmacists. See, *e.g.*, *United States* v. *Daniel*, 3 F.3d 775, 778 (4th Cir. 1993), cert. denied, 510 U.S. 1130 (1994); *United States* v. *Kaplan*, 895 F.2d 618, 619 (9th Cir. 1990); *United States* v. *Jamieson*, 806 F.2d 949, 951 (10th Cir. 1986); *United States* v. *Chin*, 795

F.2d 496, 503 (5th Cir. 1986); *United States* v. *Hammond*, 781 F.2d 1536, 1537 (11th Cir. 1986); *United States* v. *Plesons*, 560 F.2d 890, 896-897 & n.6 (8th Cir. 1977); accord *United States* v. *Hughes*, 895 F.2d 1135, 1143 (6th Cir. 1990) ("legitimate medical practice").[6]

In fact, Congress has adopted a statutory definition of "valid prescription" that mirrors the Attorney General's. In 2000, Congress revised the reporting requirements for distributions of certain listed chemicals. See Children's Health Act of 2000, Pub. L. No. 106-310, Tit. XXXVI, Div. B, § 3652, 114 Stat. 1239 (21 U.S.C. 830(b)(3)). In so doing, Congress exempted from the reporting requirements "[d]istributions * * * pursuant to a valid prescription." 21 U.S.C. 830(b)(3)(D)(iv). Congress defined the phrase "valid prescription" in terms almost identical to those used by the Attorney General regarding the requirement for a "prescription" under 21 U.S.C. 829(a) and (b), as one "issued for a legitimate medical purpose by an individual practitioner * * *

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[6] The phrases "legitimate medical purpose," 21 C.F.R. 1306.04(a), and "in the course of professional practice," 21 U.S.C. 802(21), both reflect a concern for allowing only legitimate or professionally appropriate uses of controlled substances and reflect essentially the same standard. See, *e.g.*, *Daniel*, 3 F.3d at 778 (allegation that drug distributions were not "for a legitimate medical purpose" was sufficient to allege that they fell "outside the boundaries of the registrant's professional practice"); *United States* v. *Kirk*, 584 F.2d 773, 784 (6th Cir.) ("[T]here is no difference in the meanings of the statutory phrase, 'In the usual course of professional practice' and the regulations' phrase, 'legitimate medical purpose.'"), cert. denied, 439 U.S. 1048 (1978); *Plesons*, 560 F.2d at 897 n.6 (same); *United States* v. *Rosenberg*, 515 F.2d 190, 196-197 (9th Cir.) (phrases "not 'in the usual course of professional practice' and not 'for any legitimate medical or research purposes'" "have essentially the same meaning"), cert. denied, 423 U.S. 1031 (1975); *United States* v. *Nelson*, 383 F.3d 1227, 1231 (10th Cir. 2004) (noting that "there is considerable room to doubt" whether the phrases "outside the usual course of medical practice" and "without legitimate medical purpose" have different meanings). Cf. *United States* v. *Tran Trong Cuong*, 18 F.3d 1132, 1138 (4th Cir. 1994) (stating the "legitimate medical purpose" standard is, if anything, more favorable to the defendant than the standard stated in *Moore*).

acting in the usual course of the practitioner's professional practice," 21 U.S.C. 830(b)(3)(A)(ii).

B. The Attorney General's Conclusion That Facilitating An Individual's Suicide Is Not A "Legitimate Medical Purpose" In "Treatment" For Purposes Of The Controlled Substances Act Is Supported By The Overwhelming Weight Of Authority

The overwhelming weight of authority supports the Attorney General's conclusion that dispensing drugs for the purpose of hastening a person's death is outside "the usual course of professional treatment" and not a "legitimate medical purpose" under the federal regulatory scheme. 21 C.F.R. 1306.04. The Attorney General's conclusion is supported by the ordinary meaning of the CSA's text and by centuries of almost uniform opposition to the practice of assisted suicide, including the current opposition of leading medical societies, federal law, and the law of 49 of the 50 States. In light of the deference owed to the Attorney General's construction of the CSA, this broad consensus amply supports the reasonableness of his conclusion.

1. The language of the CSA demonstrates that Congress did not authorize physicians to prescribe controlled substances for the purpose of ending their patients' lives

As explained above, the operative requirements for a "prescription" to be valid under the CSA are that it be issued for a "legitimate medical purpose" and "in the usual course of professional treatment." 21 C.F.R. 1306.04(a). See 21 U.S.C. 830(b)(3)(A)(ii). Because the CSA and implementing regulations do not specifically define those terms, they should be given their "ordinary meaning." See, *e.g.*, *Asgrow Seed Co.* v. *Winterboer*, 513 U.S. 179, 187 (1995); *FDIC* v. *Meyer*, 510 U.S. 471, 476 (1994). The ordinary meaning of the term "medical" is "[p]ertaining or related to the healing art or * * * to 'medicine,'" 9 *Oxford English*

Dictionary 546 (2d ed. 1989), and the term "medicine" refers to "[t]hat department of knowledge and practice which is concerned with the cure, alleviation, and prevention of disease in human beings, and with the restoration and preservation of health," *id.* at 549; see *Webster's Third New International Dictionary* 1402 (1966) ("the science and art dealing with the maintenance of health and the prevention, alleviation, or cure of disease"); *The Random House Dictionary of the English Language* 1194 (2d ed. 1987) ("the art or science of restoring or preserving health or due physical condition"). Whatever else the provision of controlled substances for the express purpose of hastening death may constitute, it clearly crosses a line and involves something other than the restoration or preservation of health, *i.e.*, involves something other than medicine. Indeed, in one of this Court's first decisions to construe the Harrison Act of 1914, ch. 1, 38 Stat. 785 (Harrison Act)—the precursor to the CSA—the Court held that the term "prescription" by itself plainly connoted a requirement that the physician be attempting to "treat[]" or "cure" an illness. See *Webb* v. *United States*, 249 U.S. 96, 99-100 (1919) (To call a doctor's order for morphine that was "not * * * issued * * * in the course of professional treatment in the attempted cure of the habit" "a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required."). Assisting an individual's suicide does not fit within the ordinary meaning of the phrases "legitimate medical purpose" or "usual course of professional treatment," 21 C.F.R. 1306.04(a), because it does not aim to preserve the patient's health or to cure, alleviate, prevent, or "treat" the disease or its symptoms in the patient. To the contrary, it aims to bring about the patient's death.

Moreover, the context within which these phrases are used within the CSA confirms that Congress intended them to be construed according to their ordinary usage. For ex-

ample, the legislative findings that accompany the CSA reflect that Congress associated "legitimate medical purpose" with "maintain[ing] the health and general welfare of the American people." 21 U.S.C. 801(1). Similarly, Congress's direction that controlled substances be scheduled according to whether they have a "currently accepted medical use *in treatment*" and an "accepted *safety* for use * * * under medical supervision," 21 U.S.C. 812(b) (emphasis added), reflects Congress's intent that physicians dispense controlled substances to preserve and enhance—not end—their patients' lives. It certainly makes no sense to talk about the "safety for use" of drugs when they are dispensed to end a person's life. "A doctor who assists a suicide * * * 'must, necessarily and indubitably, intend primarily that the patient be made dead.'" *Vacco* v. *Quill*, 521 U.S. 793, 802 (1997) (quoting *Assisted Suicide in the United States: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 104th Cong., 2d Sess. 367 (1996) (testimony of Dr. Leon R. Kass)). The CSA's repeated use of the word "medical" in conjunction with the words "treatment," "health," and "safety" confirms that suicide is not a "legitimate medical purpose" under the CSA, because any procedure intended to cause the death of a patient is not "treatment" and does not promote the patient's "health" or "safety."[7]

[7] The Attorney General's interpretive ruling distinguishes between a physician who intentionally brings about his patient's death and one who treats the pain associated with illness, even though such treatment may have the unintended consequence of hastening the patient's death. Pet. App. 103a. See *Vacco*, 521 U.S. at 802 (noting the significance of this distinction).

2. The Attorney General's interpretation of the phrases "legitimate medical purpose" and "professional treatment" to exclude physician-assisted suicide is supported by historical tradition and the near-unanimity of state and federal authority

Even if the provisions of the CSA were not themselves clear, deference is owed to the Attorney General's construction of the Act and the implementing regulation describing what constitutes a valid prescription for purposes of federal law. See *Chevron U.S.A. Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 843-844 (1984). The Attorney General, and his delegee the Administrator of the DEA, are, after all, the federal officers with primary responsibility for enforcing the CSA. See *Alliance for Cannabis Therapeutics* v. *DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991) ("neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable"); *Trawick* v. *DEA*, 861 F.2d 72, 75-76 (4th Cir. 1988) (deferring to DEA Administrator's determination that registrant's actions were inconsistent with the public interest and that his registration should be revoked). Indeed, the Attorney General's interpretation of his own regulation, 21 C.F.R. 1306.04, is entitled to particular deference under *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997), and *Thomas Jefferson University* v. *Shalala*, 512 U.S. 504, 512 (1994).

The Attorney General's conclusion—that the provision of drugs for the express purpose of ending life is something other than legitimate medical treatment—is consistent with the position adopted by 49 States, the federal government in other contexts, and leading associations of the medical profession. As the Court noted in *Washington* v. *Glucksberg*, 521 U.S. 702 (1997):

> In almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide. The States' assisted-suicide bans are not innovations. Rather, they are longstanding expressions of the States' commitment to the protection and preservation of all human life.

Id. at 710. See *id.* at 710 n.8 (citing compilation of state authorities); *id.* at 776 n.14 (Souter, J., concurring) (citing state statutes expressly prohibiting assisting a suicide).[8] The laws of all 49 states, apart from Oregon, express their disapproval in one form or another of assisted suicide. See *ibid.*; *Vacco*, 521 U.S. at 805-806 & n.9 (collecting health-care and living-will statutes of 49 States and two territories disapproving of suicide and assisted suicide). It is Oregon's physician-assisted suicide statute that is contrary to longstanding historical practices as well as to the contemporary state of the law. *Glucksberg*, 521 U.S. at 710-719; *id.* at 723 ("[W]e are confronted with a consistent and almost universal tradition that has long rejected [a right to physician-assisted suicide], and continues explicitly to reject it today, even for terminally ill, mentally competent adults.").[9] Oregon is free to change its state law; but doing so does not require the Attorney General to change his interpretation of federal law.

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[8] Since *Glucksberg* was decided, Maryland and South Carolina have passed statutes expressly prohibiting assisted suicide. See Md. Code, Crim. Law § 3-102 (Michie 2002); S.C. Code Ann. § 16-3-1090 (2003). In addition, West Virginia and Wyoming have adopted new statutes that expressly provide that laws permitting the withdraw of medical treatment do not authorize assisted suicide. See W. Va. Code § 16-30-15 (Michie 2001); 2005 Wyo. Laws ch. 161 (H.B. 107) (to be codified at Wyo. Stat. § 35-22-414(c)). Virginia and Ohio have passed statutes declaring their opposition to assisted suicide and authorizing their courts to enjoin the assistance of suicide. Va. Code Ann. § 8.01-622.1 (Michie 2000); Ohio Rev. Code Ann. § 3795.02 (Page 2003 Supp.).

[9] Indeed, Oregon as well criminalizes assisting another's suicide if done by anyone other than a physician acting pursuant to the DWDA. See Or. Rev. Stat. § 163.125(1)(b) (2003); *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994).

The Attorney General did not ignore the laws of the States in interpreting the CSA to bar the dispensing of controlled substances to facilitate suicide. To the contrary, his interpretation is consistent with the position of the overwhelming majority of the States. In light of the historical unanimity of opinion on this issue, and the fact that the CSA predated Oregon's DWDA by several decades, it is inconceivable that Congress, in enacting the CSA, regarded assisted suicide as a legitimate "medical" practice in the "treatment" of disease.

Numerous health care experts have likewise agreed that physician-assisted suicide is not a legitimate medical treatment. In *Glucksberg*, the Court noted that New York State's Task Force on Life and the Law—a group including doctors, ethicists, lawyers, religious leaders and interested laypersons—had unanimously concluded that "[l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable. . . . [T]he potential dangers of this dramatic change in public policy would outweigh any benefit that might be achieved." 521 U. S. at 719 (quoting New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 120 (May 1994)). Likewise, as OLC noted in the memorandum on which the Attorney General's interpretive ruling was based, the American Medical Association (AMA), American Nurses Association, and American Psychiatric Association filed a joint brief in *Glucksberg* taking the position that physician-assisted suicide is "fundamentally incompatible with the physician's role as healer." Pet. App. 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)); see *Glucksberg*, 521 U.S. at 731 (quoting same). The ethical guidelines of the AMA continue to state that "[p]hysician assisted suicide is fundamentally incompatible with the physician's role as healer." AMA, *Current Opinions of the*

Council of Ethical and Judicial Affairs, Opinion No. E-2.211, Physician-Assisted Suicide (last visited Apr. 28, 2005) <http://www.ama-assn.org/ama/pub/category/print/8459. html>.

In other federal laws and programs as well, physician-assisted suicide is not regarded as a legitimate medical practice. In 1997, Congress passed a broad ban on the federal funding of assisted suicide. See Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, § 3(a), 111 Stat. 23. Administratively, the Department of Health and Human Services's Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) similarly has determined that physician-assisted suicide is not eligible for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." Pet. App. 121a (internal quotation marks omitted); *Medicare Benefit Policy Manual* ch. 16, § 20 (2003).

There can be no question, then, that the Attorney General's interpretive ruling is consistent with the prevailing legal and medical views regarding medical practice and on that basis is, at the very least, a reasonable interpretation of federal law, which is entitled to deference.

C. The Controlled Substances Act Has A Uniform Meaning, Determined By Federal Law, Throughout The United States

As the court of appeals recognized, the principal question presented by this case is "who gets to decide," Pet. App. 9a, whether particular conduct comports with the federal requirement under the CSA that a prescription be issued for a "legitimate medical purpose" and in the "usual course of professional treatment," 21 C.F.R. 1306.04(a). Although Congress presumably could develop a statutory scheme that depended entirely on state law and varied across the Nation, it did not do so in the CSA. The text and structure of the CSA, as reinforced by general principles of federalism, make clear

that a uniform federal standard determines what constitutes a legitimate medical purpose under this federal statute.

1. *There is a presumption in favor of a uniform national standard.* It is a well-established principle of statutory construction that, "in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43, 47 (1989) (quoting *Jerome* v. *United States*, 318 U.S. 101, 104 (1943), and holding that the word "domicile" used in the Indian Child Welfare Act, 25 U.S.C. 1911(a), should have a uniform meaning rather than vary according to state law). Rather, "[b]ecause federal law applies nationally," the assumption is "that Congress desires national uniformity in the application of its laws." *Salt Lake Tribune Publ'g Co.* v. *Management Planning, Inc.*, 390 F.3d 684, 688 (10th Cir. 2004). Accordingly, this Court has repeatedly adopted uniform national definitions for the terms in federal laws and refused to make the definitions of those terms dependent upon the vagaries of state law. See, *e.g.*, *Reves* v. *Ernst & Young*, 494 U.S. 56, 71 (1990) (the meaning of the word "maturity" in the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(10), "is a question of federal law" and does not differ from State to State based on differences in state law); *United States* v. *Turley*, 352 U.S. 407 (1957) (same for the word "stolen" in the National Motor Vehicle Theft Act, 18 U.S.C. 2312); *United States* v. *Pelzer*, 312 U.S. 399 (1941) (same for the phrase "future interests" in the Revenue Act of 1932, ch. 209, § 504(b), 47 Stat. 247). Because nothing in either the CSA or its implementing regulations makes the definition of "legitimate medical purpose" or "treatment" depend upon state law, this Court's decisions in *Mississippi Band* and similar cases mandate that those phrases be given uniform federal definitions and not vary from State to State.

Indeed, the *Mississippi Band* presumption is particularly appropriate with respect to the CSA, which establishes a "comprehensive federal scheme" for regulating controlled substances. *Gooding* v. *United States*, 416 U.S. 430, 449 (1974). The CSA contains numerous provisions reflecting the need for uniform minimum federal standards. Congress emphasized that when employed for a "legitimate medical purpose," controlled substances are "necessary to maintain the health and general welfare of the American people," 21 U.S.C. 801(1), but that "illegal * * * distribution * * * and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. 801(2). And Congress specifically found that "*[f]ederal* control" of all incidents of the traffic in controlled substances, including intrastate incidents, is "essential to the effective control" of such substances. 21 U.S.C. 801(6) (emphasis added). Accordingly, the core provisions of the CSA prohibit the dispensing of controlled substances "[e]xcept as authorized *by this subchapter*," 21 U.S.C. 841(a) (emphasis added), and authorize registered physicians to prescribe controlled substances only "to the extent authorized by their registration and in conformity with the other provisions *of this subchapter*," 21 U.S.C. 822(b) (emphasis added). The repeated cross-references to the provisions of the CSA itself, without any comparable references to state law, demonstrate Congress's intent to create a comprehensive federal system of regulation.

Other provisions of the CSA confirm that the requirement of a legitimate "medical" purpose in "treatment" cannot be construed as a delegation to the States to determine what constitutes legitimate medical practices for purposes of the CSA. The CSA authorizes the Attorney General to assign controlled substances to particular schedules, 21 U.S.C. 811(a), depending on whether they have "accepted *medical use in treatment in the United States*," 21 U.S.C. 812(b) (emphasis added). The CSA's scheduling provisions plainly contemplate a single national determination of accepted "medical" use; there is no such thing as a controlled substance that appears in schedule I in those States that do not recognize any accepted "medical" use for the substance but appears in a different schedule in other States that do recognize such a use. Moreover, the fact that Congress itself initially put certain drugs on schedule I—subject to rescheduling based on the judgments of federal, not state, officials—is a particularly strong indication that the Congress that enacted the CSA believed medical judgments could and should be made on the national level. See pp. 28-30, *infra*.

2. *Judicial decisions interpreting the CSA confirm that it provides a uniform federal-law standard.* This Court's decisions confirm that the minimum standards established by the CSA for dispensing controlled substances are uniform throughout the Nation and are not subject to revision by the States.[10] As the Court has recognized, "the application of federal legislation is nationwide and at times the federal program would be impaired if state law were to control." *Dickerson* v. *New Banner Inst., Inc.*, 460 U.S. 103, 119-120 (1983). The determination whether a drug has a "currently accepted medical use in treatment in the United States," for purposes of scheduling the substance under 21 U.S.C. 812(b), is such an instance in which the need for federal uniformity precludes resort to 50 different state laws.

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[10] The fact that the CSA sets national minimum standards as a matter of federal law does not mean that it preempts the entire field of controlled substances regulation. It does not. See 21 U.S.C. 903; House Report 29. The CSA does expressly preempt state law when there is a "positive conflict between [a] provision of [the CSA] and [a] State law so that the two cannot consistently stand together." 21 U.S.C. 903. In that event, however, it is state law, not federal law, that must yield. The CSA clearly creates a uniform minimum federal regulation of controlled substances; States may relax or eliminate their own state regulatory schemes or impose stricter state limits on controlled substances, but they are not free to revise the uniform federal standard.

a. In *Oakland Cannabis*, for example, the Court considered a ballot initiative passed by California voters that established, for purposes of state law, that seriously ill Californians could "use marijuana for medical purposes." 532 U.S. at 486 (quoting Cal. Health & Safety Code Ann. § 11362.5(b)(1)(A) (West 2004 Supp.)). Nonetheless, this Court rejected a marijuana cooperative's reliance on the state law as supporting a "medical necessity" defense to a federal prosecution under the CSA. The Court held that such a defense would be inconsistent with Congress's finding, in classifying marijuana in schedule I, that the substance has "no currently accepted medical use in treatment in the United States." *Id.* at 492, see *id.* at 493 (notwithstanding the California law, "Congress has made a determination that marijuana has no medical benefits worthy of an exception," and neither the State nor the Court could "override a legislative determination" to that effect).

Although Congress, rather than the Attorney General, had made the initial determination that marijuana has no generally accepted medical use in treatment in the United States, that distinction makes no difference as to the determination's binding effect on the States. Indeed, the Court expressly rejected the converse argument—that Congressional determinations were entitled to less deference—in *Oakland Cannabis*, 532 U.S. at 492-493, and the CSA expressly grants the Attorney General authority to assign substances to the appropriate schedule, and to move substances (including those originally classified by Congress) among schedules. 21 U.S.C. 811(a).

b. Just as California's ballot initiative purporting to recognize, as a matter of state law, a permissible "use [for] marijuana for medical purposes," Cal. Health & Safety Code § 11362.5(b)(1)(A), did not compel recognition in *Oakland Cannabis* of an exception to the generally applicable federal rule under the CSA that a schedule I substance has no "generally accepted medical use in treatment in the United States," such a state law would not compel the Attorney General to *reclassify* marijuana to a different schedule under the CSA. Rather, such a reclassification requires an independent *federal* assessment of the medical and scientific evidence and, if supported by substantial evidence, would bind the entire Nation for purposes of the CSA. See *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131 (D.C. Cir. 1994) (upholding DEA's refusal to reschedule marijuana as supported by substantial evidence); see also *Gettman* v. *DEA*, 290 F.3d 430, 432 (D.C. Cir. 2002) (explaining CSA procedures for rescheduling a controlled substance). As the D.C. Circuit held in *Alliance for Cannabis*, "only rigorous scientific proof can satisfy the CSA's 'currently accepted medical use' requirement." 15 F.3d at 1137. There is no basis in the CSA for substituting a ballot initiative, such as California voters' approval of medical marijuana or Oregon voters' endorsement of physician-assisted suicide, for the "rigorous scientific proof" required by the CSA for a substance to be found to have an "accepted medical use." *Ibid.*

Nor is there any reason to conclude, as the court of appeals did in this case, that the Attorney General's determination whether a *particular* use of a controlled substance qualifies as a "legitimate medical purpose" "in the usual course of professional treatment" for CSA purposes, 21 C.F.R. 1306.04(a), is any less binding in the States than his determination whether a substance has *any* accepted medical use. *Oakland Cannabis* makes clear that the Attorney General could reclassify the schedule II substances typically used by Oregon physicians to assist suicide[11] to schedule I if the medical and scientific evidence warranted—despite Ore-

[11] According to the Oregon Department of Human Services, the three drugs that have been dispensed pursuant to the DWDA are secobarbital, pentobarbital, and amobarbital, all of which are schedule II depressants. See Patients' Br. in Opp. 29a-30a; 21 C.F.R. 1308.12(e).

gon's assisted suicide initiative. There is no reason he should have less authority to determine that, while those schedule II substances have *other* generally accepted medical uses in treatment, deliberately assisting a person to commit suicide is not one of them.

The Attorney General imposed just that type of limitation on the use of a schedule II substance when he transferred the substance dronabinol (which was approved by the FDA in a particular form marketed under the brand name Marinol) from schedule I to schedule II. Dronabinol is an isomer of tetrahydrocannabinols (THC), which is the principal psychoactive substance in marijuana. 51 Fed. Reg. 17,476 (1986). After the FDA determined that Marinol has a legitimate medical use in alleviating nausea associated with cancer treatment, *id.* at 17,477, DEA issued a rule transferring the substance from schedule I to schedule II—as a drug with "a currently accepted medical use with severe restrictions," 21 U.S.C. 812(b)(2)(B); 51 Fed. Reg. at 17,476. In so doing, however, DEA recognized the significant risk that Marinol would be dispensed by physicians for improper purposes, rather than the accepted use recognized by the FDA, and that practitioners might "attempt to justify illegal or improper distribution or dispensing by claiming unique knowledge of [the] drug's effectiveness for a broad range of medical indications." *Id.* at 17,477. For that reason, at the same time DEA moved Marinol to schedule II, it also made clear that a physician who dispenses Marinol "for medical indications outside the approved use associated with cancer treatment, except within the confines of a structured and recognized research program," would be subject to revocation of his or her registration and possible criminal prosecution. *Ibid.*[12]

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[12] DEA subsequently retransferred Marinol to schedule III under the CSA. See 64 Fed. Reg. 35,928-35,930 (1999). The Federal Register notice of the final rule moving Marinol to Schedule III noted that the FDA had expanded the indications for Marinol's use to include the treatment of anorexia associated with weight loss in patients with AIDS, but that notice did not expressly continue the prior policy statement concerning restrictions on prescribing Marinol.

c. This Court's decision in *Moore* also strongly supports the conclusion that the CSA establishes a uniform *federal* standard for the permissible dispensing of substances regulated under the Act. *Moore* involved the prosecution of a physician who prescribed large quantities of methadone tablets with little or no medical assessment or supervision. See 423 U.S. at 126. He was convicted under the CSA for prescribing controlled substances outside the usual course of professional practice. The Court held that the CSA was intended to limit a physician's distribution of controlled substances to actions "as a physician" and in the course of "professional practice." *Id.* at 140, 141.

The opinion in *Moore* makes clear that Moore's conviction, which the Court affirmed, was based on a uniform nationwide standard for determining the lawfulness of the prescriptions under the CSA: Whether the prescriptions were "in accordance with a standard of medical practice generally recognized and accepted *in the United States*." 423 U.S. at 139 (quoting jury instructions) (emphasis added). The Court recognized that one of Congress's objectives in replacing the Harrison Act with the CSA was precisely to establish clear and consistent federal "limits on free experimentation with drugs" by physicians, *id.* at 143, and to clarify that "physicians who go beyond approved practice," as determined by the Secretary of Health, Education and Welfare (now Health and Human Services) and the Attorney General, are subject to criminal prosecution, *id.* at 144. See *ibid.* (noting that the CSA "requires the Secretary * * *, after consultation with the Attorney General and national addict treatment organizations, to 'determine the appropriate methods of professional practice in the medical treatment of . . . narcotic ad-

dition'" (quoting 42 U.S.C. 257a (1970), recodified at 42 U.S.C. 290bb-2a (2000)), and that those federal officials would "clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients" (quoting House Report 14, 15)).

With the exception of the decision below, the courts of appeals have followed *Moore* and applied a national standard for professional practice under the CSA. See *United States* v. *Vamos*, 797 F.2d 1146, 1151, 1153 (2d Cir. 1986) (CSA incorporates the standard of professional practice "generally recognized and accepted in the United States"), cert. denied, 479 U.S. 1036 (1987); *United States* v. *Hayes*, 794 F.2d 1348, 1351-1352 (9th Cir. 1986) ("the standard of medical practice generally recognized in the country"), cert. denied, 479 U.S. 1086 (1987); *United States* v. *Norris*, 780 F.2d 1207, 1209 & n.2 (5th Cir. 1986) (same as *Vamos*); *United States* v. *Daniel*, 3 F.3d 775, 778 (4th Cir. 1993) (same), cert. denied, 510 U.S. 1130 (1994); Kevin F. O'Malley et al., *Federal Jury Practice and Instructions (Criminal)* § 64.16, at 428 (5th ed. 2000) (same). Indeed, several courts, including the court below, have specifically rejected arguments by practitioner-defendants that their federal-law obligations under the CSA should depend on state law. In *United States* v. *Rosenberg*, 515 F.2d 190, 198 (1975), the Ninth Circuit affirmed the conviction of a California doctor under the CSA and rejected as "singularly unpersuasive" his contention that "the determination of whether or not he was acting in the course of his professional practice must be determined by the state of California." Similarly, in *United States* v. *Leal*, 75 F.3d 219 (1996), the Sixth Circuit rejected a pharmacist's defense against prosecution for violating the CSA that state law imposed no duty to identify suspicious prescriptions. *Id.* at 226-227.[13] As the Sixth Circuit held, "[w]hether state law

[13] *Leal* was later overruled on other grounds. See *United States* v. *Kennedy*, 107 Fed. Appx. 518 (6th Cir. 2004).

imposes an equivalent civil or criminal duty is irrelevant" to whether the pharmacist had violated his "federal duty * * * to be vigilant in filling prescriptions." *Id.* at 227.

3. *The CSA's legislative history confirms that there is a uniform federal-law standard.* The CSA's legislative history reflects Congress's understanding that the Harrison Act, the predecessor to the CSA, created a federal standard for determining what constitutes a legitimate medical practice and its intent to clarify that *federal* standard, not to cloud that standard by overlaying potentially disparate state standards. The House Report noted that "for the last 50 years" physicians had been subject to federal prosecution under the Harrison Act if their "methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors of what constitutes appropriate methods of professional practice." House Report 15.[14] The House Report states an intent "to clarify for the medical profession in the United States the extent to which they may safely go in treating narcotic addicts as patients," *id.* at 14, and the CSA directed the Secretary, working together with the Attorney General, to do so, 42 U.S.C. 290bb-2a (2000) (formerly codified at 42 U.S.C. 257a (1970)). The House Report leaves no doubt that Congress intended to establish a uniform *federal* standard for the use of narcotics in medical treatment, rather than to confuse standards by incorporating varying

[14] Congress's understanding of the Harrison Act was clearly correct. "What ensued soon after passage of the act can fairly be described as the most comprehensive general criminal enforcement of any law against medical professionals in U.S. history." Kurt Hohenstein, *Just What the Doctor Ordered: The Harrison Anti-Narcotic Act, the Supreme Court, and the Federal Regulation of Medical Practice, 1915-1919*, 26 J. Sup. Ct. Hist. 231, 231-232 (2001). See, *e.g.*, *United States* v. *Webb*, 249 U.S. 96 (1919); *United States* v. *Doremus*, 249 U.S. 86 (1919).

state law duties. See House Report 14-15; *Moore*, 423 U.S. at 144 (discussing same).[15]

Moreover, in subsequent amendments to the CSA, Congress has diminished the relevance of state law in the one area where the Act refers to it. As originally enacted, the CSA incorporated state law only with respect to the standards for obtaining a registration. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 303(f), 84 Stat. 1253; *Moore*, 423 U.S. at 138 n.15 ("Registration was mandatory for practitioners with state licenses."). But Congress modified those standards in 1984 to allow the Attorney General to make practitioner registration determinations on independent federal grounds, see 21 U.S.C. 823(f) (making compliance with state law only one of several factors in determining whether the public interest would be served by registering a physician), precisely because States were not adequately regulating abuses by physicians of their prescription-writing authority. See, *e.g.*, S. Rep. No. 225, 98th Cong., 1st Sess. 262 (1983) (noting that it "may clearly be contrary to the public interest" to require the Attorney General to grant a practitioner's registration application to any practitioner licensed under state law); 130 Cong. Rec. 25,849 (1984) (statement of Rep. Fish) ("State laws regarding the dispensing of controlled substances are * * * inadequate."); *id.* at 1586 (statement of Sen. Laxalt) (Congress intended to "expand[] the standards for practitioner registration beyond the * * * exclusive reliance upon

[15] The parts of the 1970 Act specific to the treatment of narcotics addiction were superseded by the Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124. The 1974 law also prescribed specific and uniform federal standards with respect to the use of controlled substances in the treatment of narcotics addiction. It requires federal registration for narcotic treatment programs, 21 U.S.C. 823(g), which is "predicated on the demonstrated ability to comply with *medical standards established by the FDA and security standards established by DEA*," H.R. Rep. No. 884, 93d Cong., 2d Sess. 4 (1974) (emphasis added).

authorization by the practitioner's own jurisdiction"); see also *id.* at 25,850 (statement of Rep. Hughes) (drugs "prescribed by physicians * * * account for about 60 percent of the overdoses each year"); *id.* at 25,851 (statement of Rep. Gilman) (physician prescriptions are responsible for the diversion of "close to 1 million doses of dangerous drugs per year" from legitimate channels to illegitimate channels). Congress wanted to "make it easier" for DEA "to suspend or revoke the authority of physicians and pharmacists who write or dispense prescriptions in a way that is threatening to the public health or safety." *Ibid.* Thus, even where the CSA had incorporated state law by reference, Congress has revised the Act to make the federal regulation of controlled substances less dependent on the varying determinations of state authorities, and thereby even more uniformly applied throughout the Nation.

The court of appeals' ruling could have a significant adverse impact on federal prosecutions of physicians under the CSA outside the context of assisted suicide and would provide even less clarity and uniformity than under the Harrison Act regime that Congress desired to replace. As noted above, the courts of appeals have, until now, recognized that the "standard of medical practice generally recognized and accepted" for purposes of the CSA, *Moore*, 423 U.S. at 139, is a national one. If, however, the Court were to hold that the CSA implicitly incorporates the views of each of the 50 States regarding acceptable practice with respect to the dispensing of controlled substances, the prosecution of physicians would become much more difficult. In most instances, there would be no state statutory law governing the particular matter in question, and defendants would be free to assert their own view of accepted medical practice in that State. See *Rosenberg*, 515 F.2d at 198 n.14 (physician's attempted defense that prescription of the drugs at issue in limited quantities was permissible under state law); *Leal*, 75

F.3d at 226-227 (pharmacist's attempted defense that state law permitted pharmacist to fill prescription without inquiring into its appropriateness).

Ironically, the court of appeals' decision presumes that Congress intended to make federal requirements under the CSA dependent upon the 50 States' different views of medical practice at precisely the same time that the States were moving away from local practice standards in favor of national ones. By 1970, when Congress enacted the CSA, the States were in the process of abandoning the "locality rule" that doctors were to be judged according to the standard of care "in the same or similar locality." Jon R. Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DePaul L. Rev. 408, 409 (1968-1969); see *id.* at 410 (noting that the rule "is about to disappear almost completely"); Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 Wis. L. Rev. 1193, 1234 ("[s]ince the 1960s, conventional wisdom has characterized the locality rule as an obsolete doctrine"). Some of the chief reasons that the States abandoned the locality rule were that it required plaintiffs to produce local experts, who might be unwilling to testify against a colleague, and that it effectively immunized doctors who, however low their standards, were the only ones in the community. Waltz, *supra*, 18 DePaul L. Rev. at 420; Silver, *supra*, 1992 Wis. L. Rev. at 1227; *Robbins* v. *Footer*, 553 F.2d 123, 128, 130 (D.C. Cir. 1977) (rejecting locality rule in the District of Columbia for similar reasons and, on that basis, vacating and remanding district court's disqualification of an expert witness who was not adequately expert in local practices). Where, as in most instances, no state statute specifies the standard of practice at issue, federal prosecutors would have to contend with all the problems that led to the rejection of the locality rule in malpractice

actions. There is nothing in the CSA, however, that supports such a result.

II. THE COURT OF APPEALS' REJECTION OF THE ATTORNEY GENERAL'S INTERPRETIVE RULING WAS BASED ON A FUNDAMENTAL MISUNDERSTANDING OF APPLICABLE PRINCIPLES OF STATUTORY CONSTRUCTION

A. The Controlled Substances Act Does Not Intrude Upon The Core Sovereignty Of The States In A Way That Implicates The Clear Statement Rule Of *Gregory* v. *Ashcroft*

Rather than follow *Oakland Cannabis*, *Moore*, and *Mississippi Band*, the court of appeals concluded that under *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), state law must control the question whether a physician's conduct constitutes a legitimate medical practice under the CSA, absent a clear statement by Congress that federal law should govern the inquiry. Pet. App. 11a. The court of appeals' holding represents a drastic and unwarranted extension of *Gregory* that would, in effect, require that virtually any exercise of federal regulatory authority satisfy a judicially-imposed "clear statement" test. There is no basis in this Court's precedents for such a rule.

The court of appeals majority had to reach back to the *Lochner*-era for support for the proposition that "direct control of medical practice is beyond the power of the federal government." Pet. App. 10a (quoting *Linder* v. *United States*, 268 U.S. 5, 18 (1925)). From that flawed premise, the court of appeals reasoned that the Attorney General's interpretive ruling "invokes the outer limits of Congress's power by encroaching on state authority to regulate medical practice." *Id.* at 12a (citing *Linder*). In the court of appeals' view, for federal law to determine the content of the Controlled Substances Act's "legitimate medical purpose" requirement would intrude upon "an area of law traditionally

reserved for state authority," *id.* at 11a, and thereby "alter the usual constitutional balance between the States and the Federal Government," *ibid.* (quoting *Gregory*, 501 U.S. at 460 (additional internal quotation marks and citations omitted)). Thus, the court concluded that, under *Gregory*, the Attorney General lacked authority to adopt the interpretive rule because the CSA did not make "unmistakably clear" that federal, rather than state, law would govern the legitimate medical purpose inquiry for purposes of federal law, *ibid.*

The court of appeals' conclusion that federal regulation of the distribution of controlled substances "alter[s] the usual constitutional balance between the States and the Federal Government" in a manner that implicate's *Gregory*'s "unmistakably clear" statement rule, Pet. App. 11a, fundamentally misunderstands that rule. *Gregory* concerned the question whether a provision in the Missouri constitution requiring state judges to retire at age 70 violated federal age-discrimination laws. 501 U.S. at 455. This Court noted that the Missouri constitutional provision at issue involved "the authority of the people of the States to determine the qualifications of their most important government officials," *id.* at 463—"an authority that lies at the heart of representative government," *ibid.* (internal quotation marks and citation omitted). *Gregory* stressed that a State's decision as to the tenure of and qualifications for its own judges was a "decision of the most fundamental sort for a sovereign entity." *Id.* at 460.

Gregory does not apply in a case in which an Act of Congress may have an effect on *private* conduct as to which a State may also have its own, potentially differing, views. By its terms, *Gregory* is limited to circumstances in which the application of federal law would encroach upon how "a State defines itself as a Sovereign." 501 U.S. at 460. And the courts of appeals, other than the Ninth Circuit in this case,

have recognized the need to restrict *Gregory* to such intrusions on a State's sovereignty. See *United States* v. *Lot 5, Fox Grove*, 23 F.3d 359, 362 (11th Cir. 1994) (noting that "the *Gregory* plain statement preemption rule is limited to federal laws impacting a state's self-identification as a sovereignty"); *Gately* v. *Massachusetts*, 2 F.3d 1221, 1230 (1st Cir. 1993) (noting that *Gregory* is limited to protecting "a core function going to the 'heart of representative government'").

Contrary to the view of the majority below, *Gregory*'s clear statement rule does not apply whenever the federal government "exercise[s] control over an area of law traditionally reserved for state authority." Pet. App. 11a. Rather, *Gregory* emphasized that the State's interest in setting the qualifications of judicial office went "*beyond* an area traditionally regulated by the States," to the core of state sovereignty. 501 U.S. at 460 (emphasis added). See *City of Edmonds* v. *Oxford House, Inc.*, 514 U.S. 725, 732 n.5 (1995) (emphasizing the same with respect to *Gregory*). The court of appeals' expansion of *Gregory* would mean that virtually every federal regulation would need a clear statement from Congress, since the States' regulatory powers encompass everything not forbidden by the Constitution. *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 311 (1981) ("[T]he reserved police powers of the States * * * are plenary unless challenged as violating some specific provision of the Constitution.").

The court of appeals' view that federal regulation of the distribution of controlled substances raises significant constitutional concerns is incorrect both as a matter of history and this Court's precedents. The application of the CSA at issue here does not encroach on "an area of law traditionally reserved for state authority," Pet. App. 11a, because, as *Glucksberg* makes clear, there *is* no tradition of State's authorizing physician-assisted suicide. 521 U.S. at 723. Similarly, with respect to controlled substances more gener-

ally, Congress has regulated prescriptions for 90 years under the CSA and its predecessor, the Harrison Act, and that regulation has always involved federal evaluation of the medical uses of controlled substances. *Moore*, 423 U.S. at 142; *Webb*, 249 U.S. at 99-100; see pp. 24-36, *supra*.

The court of appeals cited *Linder* as authority for the proposition that "direct control of medical practice in the states is beyond the power of the federal government," Pet. App. 10a, and for the further conclusion that the Attorney General's interpretive ruling "invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice," *id.* at 12a. Notably, the Court's *Lochner*-era decision in *Linder* relied upon the then-prevailing view, articulated in such cases as *Hammer* v. *Dagenhart*, 247 U.S. 251 (1918), that certain categories of conduct were beyond Congress's enumerated powers, such as its power under the Commerce Clause. *Linder*, 268 U.S. at 17 (citing *Hammer*, among other decisions, for the proposition that "an act of Congress ostensibly enacted under power granted by the Constitution, not naturally and reasonably adapted to the effective exercise of such power but solely to the achievement of something plainly within power reserved to the States, is invalid and cannot be enforced"). That holding of *Hammer* was expressly overruled in *United States* v. *Darby*, 312 U.S. 100, 115-117 (1941). The Ninth Circuit's approach threatens to resurrect the long-discredited categorical approach of *Hammer* for purposes of a clear statement test. Such an approach would prove no more workable as a matter of clear statement jurisprudence than it did as an interpretation of the Commerce Clause.

In any event, this Court's decisions applying the CSA, and similar decisions dating back to the *Linder*/*Lochner* era, establish that the federal government *can* regulate the distribution of controlled substances. *Minor* v. *United States*, 396 U.S. 87, 98 n.13 (1969) (ban on sale of narcotics is within

Congress's constitutional power); *Reina* v. *United States*, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws"). Further, the Court has made clear that *Linder* provides no defense against the prosecution of a physician under a statute enacted pursuant to Congress's constitutional powers. In *Lambert* v. *Yellowley*, 272 U.S. 581 (1926), the Court rejected a physician's argument that he was immune from prosecution under federal prohibition laws because he was distributing liquor as a "medicinal agent" and because, in the words of *Linder*, "control [over] medical practice in the states is beyond the power of the federal government." *Id.* at 596. The Court made clear that "[t]here is no right to practice medicine which is not subordinate to * * * the power of Congress to make laws necessary and proper" to its constitutional authority. *Ibid.*[16]

Subsequent decisions of the Court have further established that the CSA is binding federal law even when it renders unlawful practices deemed permissible under state law. See *Oakland Cannabis*, 532 U.S. 492-493 (upholding federal determination in the CSA that marijuana lacks an acceptable medical use, despite state law purporting to recognize such medical uses); *Moore*, 423 U.S. at 139, 141-142, 143 (recog-

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[16] In addition to *Gregory*, the court of appeals also cited *Solid Waste Agency* v. *United States Army Corps of Engineers*, 531 U.S. 159 (2001), as establishing a clear statement rule where a regulation "invokes the outer limits of Congress' power." Pet. App. 12a (quoting *Solid Waste Agency*, 531 U.S. at 172). In *Solid Waste Agency*, the Court applied the doctrine of constitutional avoidance: "Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result." 531 U.S. at 172. The "significant constitutional question[]" avoided in *Solid Waste Agency* was whether application of the Clean Water Act to "nonnavigable, isolated, intrastate waters" would be within Congress's Commerce Clause authority. *Id.* at 172-173. There is no similar constitutionally dubious application to be avoided here. As the Court held in *Minor* and *Reina*, regulation of the distribution of controlled substances pursuant to the CSA does not "invoke[] the outer limits of Congress' power" or "push the limit of congressional authority" under the Commerce Clause. *Ibid.*

nizing that "provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits," and upholding CSA conviction based upon a finding that the physician's "experiment[al] * * * theory of detoxification" was not "in accordance with a standard of medical practice generally recognized and accepted in the United States"). See also *Rosenberg*, 515 F.2d at 198 n.14 (rejecting physician's defense against CSA prosecution that prescriptions were not impermissible under state law, explaining that "[t]he question of whether federal criminal laws have been violated is a federal issue to be determined in federal courts"); *Leal*, 75 F.3d at 227 (rejecting a pharmacist's defense that state law imposed no duty to identify suspicious prescriptions because "[w]hether state law imposes an equivalent civil or criminal duty is irrelevant" to whether the pharmacist violated his "federal duty" under the CSA).

Beyond the area of controlled substances, Congress has extended federal regulatory authority over other subject matters that also may have an impact on the practice of medicine. The federal government has regulated the composition and labeling of drugs since 1906, and medical devices since 1938, see *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475-476 (1976), and does so in a manner that turns on federal determinations regarding the safety and effectiveness of those medical products or devices. See, *e.g.*, 21 U.S.C. 355(d) (requiring FDA to deny application for new drug that has not been determined to be safe and effective for its intended purpose); 21 U.S.C. 352(j) (2000 & Supp. II 2002) (drug is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"). The federal Medicare program also establishes federal standards for "medically necessary" treatment. 42 U.S.C. 1320c-5(a)(1) and (b) (requiring any "health care practitioner" participating in Medicare to provide only "medically

necessary" services to Medicare beneficiaries, and allowing the Secretary to bar violators from participating in the Medicare program); 42 U.S.C. 1395y(a)(1)(A) (2000 & Supp. I 2001) (authorizing Medicare to reimburse only "reasonable and necessary" medical services).

In short, Congress often attaches consequences under federal statutes to a determination by a federal official regarding what constitutes proper, necessary, safe, or effective medical care. See *Medtronic*, 518 U.S. at 475 ("Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people."). The uniform application of such statutory schemes is cast into doubt by the court of appeals' decision in this case.

B. The Presumption Against Preemption Of State Law Furnishes No Basis For Refusing To Give Uniform Effect To A Provision Of Federal Law

In addition to the clear-statement rule of *Gregory*, the court of appeals also invoked a presumption against federal preemption of state law as a reason to invalidate the Attorney General's interpretive ruling. See Pet. App. 14a-15a (citing *California Div. of Labor Standards Enforcement* v. *Dillingham Constr. N.A., Inc.*, 519 U.S. 316, 325 (1997)). That presumption is inapposite here because the question is whether the Attorney General's interpretive ruling about the meaning of a prescription *for purposes of federal law* is valid, not whether it preempts Oregon's assisted suicide law. When a "state statute is pre-empted by federal law," it is thereby rendered "invalid under the Supremacy Clause of the Constitution." *California Fed. Sav. & Loan Ass'n* v. *Guerra*, 479 U.S. 272, 280 (1987). There is simply no issue of preemption or the Supremacy Clause in this case. At most, there is a concern that the federal law frustrates the purposes of Oregon's voter initiative. As Oregon has conceded,

the Attorney General's interpretive ruling "does not suggest that the [Oregon law] is invalid. He asserts only that his authority over controlled substances allows him to prevent * * * use [of such controlled substances] for purposes authorized by the Oregon law." Or. Br. in Opp. 9 n.7. Oregon's law remains valid and continues to have the effect of "exempt[ing] physicians who comply with the provisions of the * * * from prosecution under [Or. Rev. Stat. § 161.125(b)(1) (2003)]," which otherwise makes it a crime under state law for anyone, including a physician, to aid a suicide. *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994). Moreover, to the extent doctors in Oregon dispense substances other than those regulated under the CSA to hasten their patients' deaths, the Attorney General's interpretive ruling has no relevance to their conduct.

Oregon's de-criminalization law for physician-assisted suicide is no more preempted than California's laws de-criminalizing the possession and use of marijuana for medical purposes was preempted in *Oakland Cannabis*. Both state statutes have undeniable effects on state law. But despite their ability to remove parallel and duplicative state-law prohibitions, States are not free to displace the federal-law duty to comply with the CSA. See *Oakland Cannabis*, 532 U.S. at 494-495 (CSA precludes "medical necessity" defense, despite a California law recognizing marijuana's purported medical utility). The continued existence of the federal-law prohibition may frustrate the achievement of the full purposes of the change in state law, but that has never been enough to raise a concern about preemption. Such a view would stand the Supremacy Clause on its head, presumptively "preempting" federal law whenever it frustrated the purposes of state law.[17]

[17] The Ninth Circuit's *Linder* analysis can be understood as a kind of reverse field preemption, at least for clear statement purposes, and its presumption against preemption analysis can be understood as a kind of reverse conflict preemption analysis. Both stand the relevant Supremacy Clause analysis on its head.

C. The Additional Reasons Given By The Court Of Appeals For Invalidating The Attorney General's Interpretive Ruling Are Also Flawed

1. The court of appeals suggested that the Attorney General's interpretation was not entitled to deference because Congress intended to limit the CSA "to the field of drug abuse and addiction." Pet. App. 23a; accord *id.* at 13a-14a & n.7, 17a, 24a. As an initial matter, the taking of drugs to commit suicide *is* a form of "drug abuse." Congress intended that controlled substances be used for "medical" purposes, a word that connotes cure, amelioration, treatment, or prevention of disease. See pp. 18-19, *supra*. Indeed, a necessary condition under the CSA for a controlled substance to be dispensed by a physician is that it have a "currently accepted *medical* use in *treatment* in the United States." 21 U.S.C. 812(b) (emphasis added). And the term "drug" is itself defined in federal law as an article intended for "diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. 321(g)(1)(B); see 21 U.S.C. 802(12) (incorporating definition of Section 321(g)(1)). Thus, by definition, intentional use of a drug to take a life, rather than for one of the purposes identified in the statute, is a form of drug "abuse."

Moreover, in enacting the CSA, Congress expressly stated its goals broadly as encompassing "illegal importation, manufacture, distribution, and possession and *improper use* of controlled substances." 21 U.S.C. 801(2) (emphasis added). A Congress concerned with fatal overdoses, House Report 34, could hardly be unconcerned with intentional overdoses. Indeed, there is no doubt that Congress viewed the use of controlled substances for suicide to be a form of abuse or improper use. The House Report specifically referred to the "[m]isuse of a drug in suicides and attempted suicides," and noted that "injuries resulting from unsupervised use are re-

garded as indicative of a drug's potential for abuse." *Id.* at 35; see *id.* at 34 (potential for abuse indicated by "evidence that individuals are taking the drug * * * in amounts sufficient to create a hazard to their health") (internal quotation marks and citation omitted); 21 U.S.C. 801(1) (noting congressional purpose "to maintain the health and general welfare of the American people"); 21 U.S.C. 823(f)(5) (requiring the Attorney General to consider threats to "the public health and safety" in issuing and revoking registrations of physicians to distribute controlled substances).

2. The court of appeals also stated that the Attorney General's interpretive rule was beyond his authority because it intruded upon the role of the Secretary of Health and Human Services under the CSA. See Pet. App. 15a, 17a-19a & n.10. The CSA does expressly assign certain functions with respect to its implementation to the Secretary, but the Attorney General shares a role even in many of those functions. *E.g.*, 21 U.S.C. 811 (allocating to both the Attorney General and the Secretary responsibility for assessing factors in subsection (c) for scheduling a substance); 21 U.S.C. 823(f) (assigning to both the Secretary and the Attorney General roles in assessing proposed research projects relating to schedule I drugs). However, many other responsibilities under the CSA that require making determinations respecting the "legitimate medical use" of substances are assigned to the Attorney General alone. For example, under 21 U.S.C. 823(a)(1), the Attorney General is responsible for ensuring an adequate supply of schedule II substances for "legitimate medical * * * purposes," which obviously requires that he first determine what are such legitimate purposes. Similarly, only the Attorney General can determine whether a physician has violated federal drug laws or engaged in activities that threaten the public health and safety for the purpose of making registration decisions under the Act. See 21 U.S.C. 823(f), 824(a)(4). Thus, the court of appeals' categorical statement that only the Secretary may "make medical decisions under the Act," Pet. App. 18a, is incorrect. In any event, the determination whether dispensing drugs to facilitate suicide constitutes a "legitimate medical use" in "treatment" is a legal issue that turns on an interpretation of the CSA and a regulation of the Attorney General, and does not require an assessment of technical medical or scientific evidence of the sort that the CSA has assigned to the Secretary in other contexts.

The court of appeals cited (Pet. App. 15a) this Court's reference in *Moore* to the Secretary's function in determining "the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction." 423 U.S. at 144 (quoting 42 U.S.C. 257a (1970) (recodified at 42 U.S.C. 290bb-2a (2000)). That provision is not at issue here. Moreover, the fact that that provision expressly confers certain medical-related responsibilities on the Secretary reinforces the conclusion that the Attorney General is solely responsible for administering and interpreting provisions of the CSA and its implementing regulations where, as here, the relevant provisions do not give the Secretary any comparable role.[18]

The court of appeals also cited legislative history that it believed supported the conclusion that the Secretary is the

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[18] Even if the Secretary were the appropriate decision-maker with respect to whether physician-assisted suicide is a "legitimate medical purpose" in the usual course of professional "treatment," that conclusion would not support the court of appeals' judgment. The OLC memorandum on which the Attorney General based his interpretive ruling explained that the Secretary, through the Centers for Medicare and Medicaid Services, had already determined that physician-assisted suicide is "not reasonable and necessary to the diagnosis and treatment of disease or injury." Pet. App. 120a-121a (quoting the policy that physician-assisted suicide is not eligible for reimbursement under Medicare); *Medicare Benefit Policy Manual* ch. 16, § 20 (2003). Thus, there is no conflict between the Attorney General's interpretive ruling and the views of the "principal health agency of the federal government." Pet. App. 18a.

appropriate decision-maker for medical issues under the CSA. Pet. App. 18a-19a. That reliance was misplaced. In the first place, the statements referred to by the court actually *confirm* the government's position here that medical standards under the CSA are uniform *federal* standards. They thereby undermine the court of appeals' principal rationale in this case—that those standards are governed by state law. For example, the House Report on the CSA stressed, with respect to "having federal officials determine the appropriate method of the practice of medicine," that "this section will provide guidelines, determined by the principal health agency of the *federal government*." Pet. App. 18a (quoting House Report 15) (emphasis added). Likewise, as the court of appeals noted, the House Report on the 1974 amendments to the CSA stated that "[a]ll decisions of a medical nature are to be made by the Secretary [of Health and Human Services]." *Id.* 19a (quoting H.R. Rep. No. 884, 93d Cong., 2d Sess. 6 (1974) (court of appeals' emphasis omitted)). Those passages leave no doubt that Congress understood the CSA to establish *federal* policy with respect to the medical decisions relevant to the statute's implementation.

Further, the legislative history cited by the court of appeals concerns the statutory provisions that expressly assign to the Secretary the responsibility for establishing methods of professional practice in the medical treatment of narcotic addiction. See p. 47, *supra*. Like the statutory provisions it describes, that legislative history further demonstrates that when Congress desired to made the Secretary the official responsible to set federal standards under the CSA, it did so expressly. The necessary implication is that, with respect to those responsibilities under the CSA that Congress assigned to the Attorney General, without reference to the Secretary, it is the Attorney General who interprets the Act and establishes the uniform federal standards for implementing the Act.

Finally, it is clear that the proper allocation of authority among federal actors was not the basis of the court of appeals' decision. If it had been, the proper resolution would have been to remand the question to the Attorney General to solicit the views of the Secretary. Instead, the court of appeals continued the district court's permanent injunction of the Attorney General's interpretive ruling. In fact, in a footnote, the court of appeals recognized that it's holding also precludes the Secretary from making a determination whether physician-assisted suicide is a "legitimate medical practice" under the CSA. Pet. App. 17a n.10. Thus, the lower court's discussion of the CSA's allocation of authority between the Attorney General and the Secretary is ultimately irrelevant to its decision.

3. The court of appeals' conclusion that the Attorney General violated 21 U.S.C. 823(f) by failing to consider all of the factors addressed in that section is also flawed. By its terms, Section 823(f) applies only to actions by the Attorney General to deny or revoke a CSA registration. The Attorney General's ruling at issue here is not such a denial or revocation. It is, rather, an interpretation of the *substantive* provisions of the Act, violation of which may in turn lead to a revocation of registration. In any event, Section 823(f) requires the Attorney General to consider a number of factors, including both compliance with state laws, 21 U.S.C. 823(f)(4), and others, such as "[c]ompliance with applicable * * * Federal * * * laws" applicable to controlled substances, 21 U.S.C. 823(f)(4), and any threat to the public health and safety, 21 U.S.C. 823(f)(5), that plainly call for an independent determination by the Attorney General. The court of appeals' ruling would preclude the Attorney General from exercising his statutory responsibility to ascertain whether a physician's registration is consistent with the public interest by requiring the Attorney General to make one factor—compliance with state law—determinative of

that question, and indeed determinative of the question whether dispensing drugs to facilitate suicide even violates the CSA in the first place. There is no support in the CSA's text and purposes for those extraordinary conclusions.[19]

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be reversed, and the case remanded with instructions to dissolve any injunctions and dismiss.

Respectfully submitted.

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[19] The court of appeals also stated, without explanation, that the Attorney General's construction of 21 C.F.R. 1306.04 was not entitled to deference because it conflicted with this Court's interpretation of that provision in *Moore*. See Pet. App. 22a. That characterization of *Moore* is difficult to comprehend. *Moore*'s only substantive discussion of Section 1306.04 (then Section 306.04) notes with approval that the regulation "makes * * * explicit" the "medical purpose requirement" implicit in 21 U.S.C. 829's requirement of a "prescription." 423 U.S. at 136-137 nn.12 & 13. That conclusion is fully consistent with the Attorney General's interpretation of his regulation at issue here. The discussion on the particular page of the *Moore* opinion referred to by the court of appeals, Pet. App. 22a (citing 423 U.S. at 144), confirms that "physicians who go beyond approved practice remain subject to serious criminal penalties." That too is entirely consistent with the Attorney General's position here.